K090828

JUL 2 8 2009

ATTACHMENT H

1.0 SMDA 510 (K) SUMMARY

2.0 Submitter

ULTRAWIN SDN BHD
Lot 2, Persiaran Perindustrian Kanthan 2,
31200 Chemor, Perak, Malaysia.

Tel 605-2013888

Fax 605-2011818

Name of Contact Person Mr. MAH SIEW HOE

Official Correspondence

Date of Summary Prepared

3.0 Name of Device

Trade Name : Non-Sterile Powder Free Nitrile Examination Gloves

Common Name : Synthetic Rubber Examination Gloves

Classification Name : Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Devices

Powder Free Nitrile Examination Gloves as described in this 510k Notification is substantially equivalent to the current Class I patient examination glove bearing the product code 80LZA (21 CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D6319-00a, Standard Specification for Nitrile Gloves for Mediacal Application.

5.0 Description of the Device

Powder Free Nitrile Examination Gloves meets all the current specifications listed under the ASTM Specification D6319-00a, Standard Specification for Nitrile Examination Gloves for medical Application.

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6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

7.0 Summary of Performance Data :

Performance data of gloves based on ASTM D6319-00a and FDA 1000ML watertight test.

TEST	ASTM D 6319-00a	POWDER FREE NITRILE EXAMINATION GLOVES
1. Watertight (1000ml)	Multiple Normal GI AQL =2.5	Pass GI AQL=2.5
2. Length (mm) Size XS S M L XL	 Min 220 Min 220 Min 230 Min 230 -	240 mm minimun for all sizes
3. Palm width (mm) Size XS S M L XL	 70±10 80±10 95±10 111±10 -	 73-78 83-88 93-98 103-107
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.05 Min 0.05	 Min 0.08 Min 0.08
5. Physical Properties Before Aging Tensile Strength (Mpa) Ultimate Elongation (%) After Aging Tensile Strength (Mpa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 15 – 21 550 – 630 14 – 22 520 – 610
6. Powder Content	Max 2.0mg/glove	Below 2 mg/glove

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8.0 The performance data of the gloves as shown above meet the ASTM D6319-00a Standard and FDA's requirement.
Powder content is below 2 mg per glove which meet the FDA Requirments.

9.0 The Bicompatibility Test consits of Primary Dermal Irritation Test and Guines Pig Sensitization test.

10.0 Conclusion

We conclude that the Mutiple Private Labeled Non-Sterile Powder Free Nitrile Examination Gloves meets :

- ASTM D6319-00a Standard
- FDA pinhole requirements
- Are below the maximum Powder Residual Content as specifed in ASTM D6319-00a.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2009

Mr. Mah Siew Hoe
General Manager
Ultrawin Sdn Bhd
Lot 2, Pesiaran Perindustrian, Kanthan 2,
31200 Chemor, Perak Darul Ridzuan
MALAYSIA

Re: K090828
Trade/Device Name: Powder Free Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 13, 2009
Received: July 16, 2009

Dear Mr. Hoe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Applicant: ULTRAWIN SDN BHD

510K Number: K090828

Device Name: Powder Free Nitrile Examination Gloves

Indications for Use:

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use .....No..... OR Over-The-Counter .....Yes.....
Per 21 CFR 801.109

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090828